IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT APPLICATION EXAMINING OPERATIONS

Appl. No.	:	10/516,405	Confirmation No. 2828
Applicant	:	Demmer *et al.*	
Filed	:	November 30, 2004	
Title:	:	Membrane, Device And Method For Removing Proteases From Liquids	
TC/A.U.	:	1651	
Examiner	:	Fernandez, Susan Emily	
Docket No.	:	9013.0099	
Customer No.	:	00152	

APPEAL BRIEF

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December 13, 2010

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Real Party in Interest

The real party in interest is the assignee Sartorius Stedim Biotech GmbH, a German corporation.

Related Appeals or Interferences

Serial No. 11/436,861 is a divisional of the instant application and is on appeal from a final rejection by the same Examiner.

Status of Claims

Claims 1-10, 12-13 and 16 have been cancelled. Claims 11 and 14-15 stand rejected and are appealed. A copy of all pending claims is set forth in Claims Appendix.

Status of Amendments

The last amendment, filed September 23, 2009, has been entered.

Summary of Claimed Subject Matter

The invention claimed in independent claim 11, from which claims 14-15 depend, is a device for removing proteases from biological fluids and pharmaceutical solutions comprising a housing with a fluid inlet and a fluid outlet, the housing containing a plurality of functionalized microporous membranes arranged in series wherein the membranes each "consist essentially of" a microporous membrane containing epoxy groups that are chemically coupled to at least one protease inhibitor via the epoxy groups wherein the protease inhibitor is selected from pepstatin, bestatin, diprotin, antipain, chymostatin, leupeptin, E64, TLCK and p-aminobenzamidine (page 4, lines 15-24; FIG. 1).

Claim 14 adds the limitation that each of the membranes contains two different protease inhibitors (page 4, lines 6-9).

Claim 15 is directed to a method for removing proteases from fluids comprising feeding a protease-containing fluid to the device of claim 14 (page 2, lines 31-32; Examples 1 and 2).

Grounds of Rejection to be Reviewed on Appeal

There are two issues for review:

(1) whether the obviousness rejection of claim 11 based on the combination of **Zeng** et al, and **Longlotz** et al, is well-founded; and

(2) whether the obviousness rejection of claims 11 and 14-15 based on the combination of **Hermanson** et al, **Zeng**, **Langlotz** and **Preece** et al. is well-founded.

ARGUMENT

Prior Art Relied Upon

Zeng discloses the incorporation of multiple chitosan membranes in a cartridge having a fluid inlet and outlet. The chitosan membranes were rendered selective to the adsorption of trypsin by chemically coupling p-aminobenzamidine (PAB) to the membranes via a succinic acid spacer, the coupling taking place "between the carboxyl groups of the succinic acid and the amino groups of PAB." Abstract and Figure 1. There is no mention of the chitosan membranes containing epoxy groups and no suggestion otherwise of coupling the PAB via epoxy groups.

Langlotz discloses covalently coupling the proteins protein A and rabbit IgG to membranes containing epoxy groups. Page 108, left column, 6th paragraph. There is no discussion whatsoever of the chemistry involved in the coupling; in other words, the covalent bond is not identified.

Hermanson discloses in pertinent part the immobilization of PAB to an agarose gel via a four step process to attach a "spacer arm" of either succinylated diaminodipropylamine (DAPA) or "6-AC" (unnamed reagent). Section 3.1.3.1 and FIG. 3.17. The purpose of the "spacer arm" is "to extend the ligand [PAB] some distance from the matrix." Ibid, page 167.

Preece merely discloses that all of the claimed protease inhibitors except PAB are protease inhibitors.

(1) Obviousness of Claim 11

The Examiner concedes that the primary reference Zeng does not disclose or suggest (1) membranes containing epoxy groups or (2) chemically coupling PAB to membranes via epoxy groups. Final Rejection, page 4, first full paragraph. While the secondary reference Langlotz does disclose (1), it does not disclose (2). Indeed, Langlotz merely discloses coupling two proteins (protein A and rabbit IgG) to membranes containing epoxy groups and does not even address the question of how, chemically speaking, those proteins are coupled.

On this last point, the Examiner asserts, "Please note that proteins couple to the epoxy-activated membrane via covalent binding [sic] between the amine terminal [sic] of the protein and the oxygen of the epoxy group." Final Rejection, page 4, second paragraph, last sentence. But nowhere in Langlotz may such a teaching be found. Moreover, there is no teaching or suggestion in either Zeng or Langlotz to the effect that protein A or rabbit IgG are chemically equivalent to PAB. Without more, this obviousness rejection is without merit.

(2) Obviousness of Claims 11 and 14-15

Claim 11 is the only independent claim in the application, with claims 14-15 depending therefrom; claim 15 also depends from claim 14. Thus, if claim11 is not rendered obvious by the combination of Hermanson, Zeng, Langlotz and Preece, neither are claims 14-15.

The Examiner concedes that the primary reference Hermanson does not disclose immobilization of any of the claimed inhibitors on membranes containing epoxy groups wherein the epoxy groups are chemically coupled to such inhibitors. Final Rejection, page 6, third full paragraph. The Examiner then proceeds to reiterate the teachings of the secondary references Zeng and Langlotz without offering any explanation as to how or why those two references make up this glaring deficiency of Hermanson. Ibid., pages 6-7. As to the Preece reference, the Examiner for unknown reasons cites it to support a given in this art, i.e., that eight of the nine claimed protease inhibitors are in fact known as protease inhibitors. Ibid., page 8, second paragraph.

In fact, in reaching her finding of obviousness of claims 11 and 14-15, the Examiner does not explain how Hermanson's teaching of immobilizing PAB to an agarose gel via a complex four-step process inserting a "spacer arm" between the gel and PAB comes into play, nor why one of ordinary skill would be motivated to eliminate Hermanson's "spacer arm" coupling, let alone how Hermanson would be combined with the other three references to render those claims obvious. See Final Rejection, paragraph bridging pages 8 and 9.

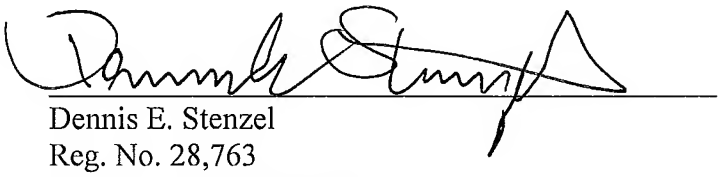
In summary, the Examiner has simply not articulated any "reasoning with some rational underpinning" to support her conclusion that the combination Hermanson, Zeng,

Langlotz and Preece renders claims 11 and 14-15 obvious. See *In re Kahn,* 78 USPQ 2d 1329 (Fed Cir 2006).

Conclusion

Because the cited prior art does not render any of claims 11 or 14-15 obvious, the final rejection of those claims should be reversed and they should all be allowed.

Respectfully submitted,



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CLAIMS APPENDIX

11. A device for removing proteases from biological fluids and pharmaceutical solutions comprising a housing having a fluid inlet and a fluid outlet, said housing containing a plurality of membranes arranged therein in series, wherein said membranes each consist essentially of a microporous membrane containing epoxy groups chemically coupled to at least one protease inhibitor via said epoxy groups, wherein said at least one protease inhibitor is selected from the group consisting of pepstatin, bestatin, diprotin, antipain, chymostatin, leupeptin, E64, TLCK and p-aminobenzamidine.

14. The device of claim 11 wherein said membranes each contain two different protease inhibitors.

15. A method for removing proteases from fluids comprising feeding a protease-containing fluid to the device of any of claims 11, 13 or 14.

EVIDENCE APPENDIX

Not Applicable

RELATED PROCEEDINGS INDEX

As noted on page 1 of this Appeal Brief, a related appeal is pending in Serial No. 11/436,861.